

K961167

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(I) **510(k) Summary:**

This summary is submitted in conformance with the format described in the 21 CFR Part 807.92 interim rule dated April 28, 1992.

(1) **Submitted By:**

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(2) **Name of Device:**

Tracheostomy Care Tray

Classification Name:

Unknown

(3) **Identification of Predicate Devices:**

Tracheostomy Care Trays

(a) Busse Hospital Disposables
Hauppauge, NY 11788

(b) Concord/Portex
Keene, NH 03431

(4) Description of Device Subject to Premarket Notification:

The Medcare Tracheostomy Care Tray is intended to provide the components necessary for the care and cleaning of tracheostomy tubes and their insertion sites. The procedure of tracheostomy care includes wound care of the stoma, oral/nasal/pharyngeal/tracheal suctioning, and tracheostomy tube or inner cannula cleaning or inner cannula replacement (in the case of a disposable inner cannula (D.I.C.) system). The kits are provided sterile, disposable, and for single patient use.

(5) Intended Use of the Device:

The MedCare Tracheostomy Care Tray is a single patient, single use, disposable device which is intended to be used for the administration of tracheostomy care.

(6) Technological Characteristics

The MedCare Tracheostomy Care Tray is similar to the predicate devices in that all of the devices provide a variety of components for the administration of tracheostomy care. All the devices provide flexibility in componentry selection for kit customization , which provides the maximum convenience for the customer.